

REMARKS

Applicant respectfully requests entry and consideration of the Amendment filed on June 18, 2003 in U.S. Application Serial No. 09/462,089. A copy of the June 18 Amendment is enclosed. Applicant also respectfully requests that the foregoing amendments be made prior to examination of the present application.

After amending the claims as set forth above, claims 1-8 and 62-83 are now pending in this application. Claims 1, 5, 66, 72, and 78-79 have been further amended to advance prosecution.

35 U.S.C. § 103

Claims 1-8 remain rejected as allegedly obvious over U.S. Patent No. 5,378,688 (Nett et al.) or Sad *et al.*, *Immunology*, 74:223-227 (1991), in view of U.S. Patent No. 5,614,487 (Battersby *et al.*) or U.S. Patent No. 5,403,586 (Russell-Jones *et al.*). Applicant addressed this rejection in the June 18 Amendment, but submits the following additional arguments.

In the Final Office Action, dated December 18, 2002, the Examiner asserts that the '688 patent "teaches a pharmaceutical composition comprising a LHRH-diphtheria toxoid conjugate for a contraceptive vaccine (See column 5, last paragraph bridging column 6, first paragraph, Claim 1 of '688 patent, in particular)." Office Action at page 5. The Examiner further asserts that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the diphtheria toxoid conjugate for a contraceptive vaccine as taught by the '688 patent." Again, Applicants respectfully traverse this rejection.

The basic premise of the present invention differs from that of the '688 patent and thus it would not have been obvious at the time of filing to make the claimed diphtheria toxoid conjugate. The '688 patent teaches "GnRH/toxin conjugate compounds and processes for using them to sterilize mammals (animals and humans) and/or for treating certain sex hormone related diseases such as cancer of the prostate or cancer of the breast." Column 5, line 67 to column 6, line 2 (emphasis added). The '688 patent discloses a diphtheria toxin and not a diphtheria toxoid. The diphtheria toxin taught in the '688 patent is produced by *Corynebacterium diphtheriae* and is lethal to humans in sub-microgram quantities. Claims 1-8 recite a diphtheria toxoid, which results from reacting diphtheria toxin with formaldehyde under carefully controlled conditions. The diphtheria toxoid lacks all toxic activity but retains the antigenicity of the native toxin. See ACADEMIC PRESS DICTIONARY OF SCIENCE AND

TECHNOLOGY, Academic Press, Harcourt Brace Jovanovich Publishers, San Diego, CA, pp. 2240 (copy enclosed). As a result, the toxoid can be safely administered to a human and is able to induce antibodies capable of neutralizing the toxin. The '688 patent requires retention of the toxicity of the toxin molecule, whereas claims 1-8 recite a toxoid which lacks toxicity. Therefore, it would not have been obvious to one of ordinary skill in the art at the time of invention to make the claimed invention.

Applicant believes that the present application is now in condition for allowance. Favorable consideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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